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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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07/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/068,812	GREFF, RICHARD J.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2007* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-38 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-38 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7/11/07* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicant's request for RCE and amendment, both filed 06/14/2007; and IDS filed 07/11/2007.

Claims 1-21, 39-41 have been canceled, and claim 42 has been added.

Claims 22-38, and 42 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/14/2007 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 34-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 34-38 are drawn to "method for decreasing the hydration time of cross-linked gelatin composition comprising steps of providing an aqueous solution, and the step of contacting gelatin with aqueous solution". Applicants are referring to paragraphs 0110, 0116, 0117, and 0130 for support for the steps of providing and contacting with aqueous solution. Recourse to these paragraphs, they describe comparison of hydration time between the gelatin of the present invention with gelatin composition not treated with the wetting agent. The samples were soaked in water to measure the hydration time, and to compare the improvement in the hydration time:

[0110] Dry samples of each of the Gelatin Compositions 2A and the Comparative Gelatin Compositions 2B and 2C were compressed to about 0.1 cm and dropped into a 250 mL beaker containing 100 mL of RO water.

[0116] Specifically, gelatin composition 3A was prepared in the same manner as gelatin composition 2A. The wetting agent coating solution comprises a selected wetting agent and a carrier solvent of either ethanol or isopropanol. Soak contact time of the foam in the wetting solution was about 10 seconds each.

[0117] After the coating layer has dried, the gelatin compositions were compressed and soaked in a 250 mL beaker containing 100 mL of RO water. The hydration times were measured as in Example 2.

[0130] The hydration times for these gelatin compositions were measured by manually compressing each cut sample and dropping it into a beaker containing 150 mL of tap water. Hydration was complete when the foam turned translucent and were measured on compressed samples, in the manner set forth in Example 2. Hydration time of a control, similar to Comparative Gelatin Example 2B, was also measured.

The specification gives no guidance to one of ordinary skill in the art regarding "method for decreasing the hydration time that require steps of providing aqueous solution, and contacting the gelatin with aqueous solution". The specification does not describe that such steps decrease the hydration time or affect or influence the hydration time of the gelatin composition by any way. The aqueous solution was used for one reason only: comparison purposes. Claiming such steps, without partial or complete description of the steps in the method of decreasing hydration time, does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. The steps are recited without any correlation does not meet the written description requirement for the claimed method of decreasing hydration time of gelatin composition as one of ordinary skill in the art could not recognize or understand method for decreasing hydration time from the mere recitation of providing and contacting with aqueous solution. Claims employing steps at the point of novelty, such as applicants', neither provide those steps required to practice the inventions, nor "inform the public" during the life of the patent of the limits of the monopoly asserted.

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. *Vas-Cath Inc. v Mahurkar*, 19 USPQ 2d 1111. The invention is, for purpose of the "written description" inquiry, what ever is now claimed (see page 1117). The specification does not clearly allow person of ordinary skill in the art to recognize that [he or she] invented what is claimed (see *Vas-Cath* at page 116).

One cannot describe what one has not conceived. See *Fiddes v Baird*, 30 USPQ2d 1481, 1483.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 34-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the relation of the steps of "providing an aqueous solution" and "contacting the gelatin composition with the aqueous solution" to the method for decreasing the hydration time of the gelatin composition.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 22-29, 34-38 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 02-182259 (259).

JP '259 teaches composition comprising cross linked gelatin, and solution comprising surfactant impregnated into the cross linked gelatin (see the provided abstract). The composition comprises 1-50 % of gelatin in aqueous solution and from 0.1 % to 30 % of the aqueous solution is the surfactant (page 5, last paragraph; page 6, first full paragraph). The reference disclosed in the process of making the composition, the gelatin solution is prepared, then, the surfactant is added followed by foaming and drying, i.e. evaporation of the solvent (page 6, second full paragraph; page 10, operational example 1). The composition easily dissolves in blood or body fluids, i.e. bioabsorbable (page 7, third line). The surfactants disclosed by the reference include sodium lauric sulfuric acid, polyethylene glycol alkyl ether and sorbitan fatty acid ester (page 7, second full paragraph). The material disclosed by the reference that comprises

cross-linked gelatin and the same wetting agent, is expected to decrease the hydration time of the cross-linked gelatin that claimed in claims 22 and 34. Furthermore, on page 5, lines 25-27 of the present disclosure, applicants disclosed that the hydration time is the time needed to prepare the gelatin for use, and the reference disclosed on page 11, third full paragraph that hemostatic composition showed slight swelling and arrested bleeding in 60 seconds, i.e. the composition was ready for use.

The difference between JP '259 and the present invention is that JP '259 does not explicitly teach coating of the wetting agent on the surface of the cross-linked gelatin. However, the reference disclosed soaking of gelatin sponge in solution wherein surfactant is added to this solution, page 6, lines 8-12). After drying the mixture of gelatin and the surfactant of the reference, it is expected to have some wetting agents on the surface of the product, which reads on partially coating. In any event, the presence of the wetting agent as a coating on the surface does not impart patentability of the claims, absent evidence to the contrary. No superior and unexpected results of record obtained by coating the wetting agent on the surface of the gelatin versus incorporating the wetting agent into the gelatin.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cross-linked gelatin sponge soaked in wetting agent as disclosed by JP '259, and it is expected to have the wetting agent on the surface of the product after drying as a partial coating.

9. Claims 30, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '259 in view of US 6,603,061 ('061).

The teachings of JP '259 are discussed above. However, JP '259 does not teach that the composition is sterilized and packaged as claimed by claim 30, or the composition comprising thrombus enhancing agent as claimed in claim 32, or antimicrobial agent as claimed in claim 33.

US '061 teaches a biocompatible hemostatic composition comprising non-hydrated cross-linked gelatin, plasticizer and hydrating agent (col.3, lines 4-6, 43, 67; col.4, lines 11-12, 41-42; col.5, line 40; col.8). The composition further comprises active agent such as antibiotics and hemostatic agents including thrombin and clotting factors (col.11, lines 16-35). The composition can be in the form of sterile package (col.3, lines 33-34; col.5, lines 6-10, 25-35; col.8, lines 32-36).

Therefore, it would have been obvious to one having ordinary skill in the art at he time of the invention to provide the hemostatic composition disclosed by JP '259 and add antimicrobial and/or clotting factors as disclosed by US '061, motivated by the teaching of US '061 that such agents are beneficial for hemostasis, with reasonable expectation of having hemostatic composition comprises cross-linked gelatin and wetting agent and further comprises antimicrobial and/or clotting factors that are beneficial for hemostasis. Additionally, one having ordinary skill in the art would have been motivated to sterilize and package the gelatin sponge produced by JP '259 as disclosed by US '061, motivated by the logic of the wound dressing art that sterilization and package of gelatin material will be safer to use on the wound or bleeding site, with

reasonable expectation of having sterile packaged gelatin sponge incorporating wetting agent that is safe to apply to bleeding site or wound.

10. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP '259 in view of EP 5568 334 ('334).

The teachings of JP '259 are discussed above. However, JP '259 does not teach that the composition comprising growth factor as instantly claimed claim 31.

EP '334 teaches collagen containing sponge comprising cross linked gelatin and active agent, preferably growth factors which enhanced wound healing and nerve regeneration (abstract; col.5, lines 22-30).

Therefore, it would have been obvious to one having ordinary skill in the art at he time of the invention to provide hemostatic composition comprising cross linked gelatin and wetting agent as disclosed by JP '259, and add growth factors to the composition as disclosed by EP '334, motivated by the teaching of US '334 that growth factors are preferred active ingredient to be added to hemostatic gelatin wound treating composition because growth factors enhance wound healing and nerve regeneration, with reasonable expectation of having composition comprising cross linked gelatin, wetting agent and growth factors wherein the composition enhances wound healing and nerve regeneration successfully.

Response to Arguments

11. Applicant's arguments filed 06/14/2007 have been fully considered but they are not persuasive. Applicants traverse the rejection over JP '259 by arguing that the cross-linking agents of the reference are not wetting agents, and the reference does not teach coating. Applicants traverse the rejection over US '61 and EP '334 by arguing that the references do not teach coating of gelatin with the wetting agent.

In response to theses argument, applicants' attention is directed to the scope of the present claims that are directed to product and method of decreasing hydration time of gelatin, and the elements of the product and the steps of the method are disclosed by JP '259. Although JP '259 does not explicitly mention the word "coating", however, coating is implied because the reference teaches mixture of the gelatin with the surfactants before drying, and it is expected that after drying the mixture the surfactant will be mixed with the gelatin sponge, and it will surround the gelatin sponge and a "partial coating" of the surfactant on the gelatin will be obtained. Regarding US '061, the reference is relied upon for teaching active hemostatic agents incorporated into wound dressing, and for teaching the packaging. EP '334 is relied upon for the solely teaching of benefit of growth factor to the wound.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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